

EU DECLARATION OF CONFORMITY

Thema Optical SRL, Via Risorgimento nr. 100, Domegge di Cadore (BL), Italia, partita IVA 00822840252 in its capacity as the manufacturer, hereby declares, under its sole responsibility, that the spectacle frame

model **IGX – 001**

in all its versions (colors and sizes):

IGX00153140091

IGX00153140097

IGX00153140098

IGX00153140101

is a class I medical device (Rule 1 Chapter III of Annex of (EU) Regulation 2017/745, which is intended for use in connection with, in the manufacturing of eyeglasses, ophthalmic lenses for correcting vision problems

Also declares that it is in conformity with the provisions of (EU) Regulation 2017/745 on Medical Devices and with the standard EN ISO 12870:2018

Domegge di Cadore, 26/05/2021

*Giorgio Valmassoi
President and Legal Representative*

Thema Optical Srl

Unique manufacturer registration number: not applicable

Basic UDI-DI: 8033852PLA01TT

Thema Optical srl

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